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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,808	04/12/2002	Etienne Honore Schacht	522-1768	1525

7590 07/13/2004  
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EXAMINER

AZPURU, CARLOS A

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 10/009,808	<b>Applicant(s)</b> SCHACHT ET AL.	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-51 and 53-57 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08212003</u> . | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

Receipt is acknowledged of the information disclosure statement filed  
08/21/2003.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite in that it fails to particularly point out what X2 entails. Clarification is requested.

Claim 50 is indefinite in that it appears to exclude hydroxy groups as functional end groups. However, it is unclear as to whether this is only when the end groups are unsaturated. Clarification is requested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1615

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36-49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 781,202 (Courtaulds Limited).

Courtaulds Limited discloses polyamides and production of polypeptides (see page 1, col. 1, lines 9-13). Among the amino acid derivatives for polymerization is anhydrocarboxyamino acid of gamma –benzyl-L-glutamate (see page 1, col. 1, lines 21-22). Various Other amino acids for possible incorporation into the polymerized form are also listed at page 1, col. 1, lines 23-31; col. 2, lines 32-35). The protective end groups of the claims are readily apparent in the written formula of isoleucine for example. Enzymatic degradation of polypeptides is inherent since deamination occurs naturally in physiological systems. The patent also goes on to state that the reaction is initiated by catalysts, of which primary amines are particularly preferred. The polymerized forms of these disclosed amino acids appear to anticipate the formulae of the claims.

Claims 50, 53, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by De Marre et al.

De Marre et al disclose polyamides and production of a polyglutamine which is suitable as a carrier for macromolecular drugs. Enzymatic degradation

of polypeptides is inherent since deamination occurs naturally in physiological systems. The claims are anticipated by De Marre et al.

Claims 38-51, 53-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Schacht et al.

Schacht et al disclose various linear and multifunctional poly aminoacids which have functional groups at either end or in the middle (see Diagrams and Example 5). The diagrams also outline the process of making the polypeptide. The method is also outlined under the "Summary of Invention" at col. 2, lines 27-65. Polyhydroxyethyl-glutamine is disclosed for use at col. 4, lines 62-63. Enzymatic degradation of polypeptides is inherent since deamination occurs naturally in physiological systems. A synthetic polymer based vehicle for delivery of nucleic acids is disclosed in the claims, and is disclosed for various treatments at col. 3, lines 6-10. The instant claims are anticipated by Schacht et al.

Claim 52 is objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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